REMARKS

This paper is responsive to the Office Action mailed May 30, 2007. All claims 1-4, 7-14, 16-24 and 29-32 were rejected in the Office Action[1].

Section 102(e) rejections.

Claims 1, 2, 7-10, 14, 16-18, 21-24, 29 and 30 were rejected under 35 U.S.C. §102(e) as being anticipated by Osypka et al (US 2003/0216771). For the following reasons, Applicants respectfully request reconsideration of these rejections.

The present invention is directed to a percutaneous entry system, and more particularly, to an insertion system for substantially bloodless percutaneous entry into a body vessel. As stated in the Background section of the present application, when medical percutaneous entry systems were originally developed, a clinician would typically insert a needle through the skin and into a body vessel, such as an artery. Visual proof that the needle tip was in the correct location was obtained when a "squirt" of blood shot out of the needle hub. As concern arose in subsequent years about the dangers of blood borne pathogens, health regulations were implemented to restrict exposure of the medical workers to blood. As a result, many devices have been developed to seek substantially bloodless entry, and thereby limit the exposure of medical personnel to blood and other body fluids. The present device represents an advancement of this technology.

Claims 1, 2, 7-10, 14 and 16.

Claim 1 of the application is directed to a percutaneous insertion system. The insertion system comprises a needle assembly, a needle hub attachment assembly, and an assembly comprising a hemostatic segment. The needle assembly has a proximal end, a distal end, and a passageway extending therebetween. The distal end

[1] According to page 1 of the Office Action Summary, claims 1-4, 7-14 and 16-32 are pending in the application. Applicants point out that claims 25-28 have previously been canceled.

of the needle assembly comprises an elongated needle for percutaneous entry into a body vessel for withdrawing a body fluid therefrom, and the proximal end comprises a needle hub. The needle hub attachment assembly has a proximal end, a distal end, and a passageway extending therebetween. The distal end of the needle hub attachment assembly is sized and configured for leak-free engagement with the needle hub. The needle hub attachment assembly includes a chamber communicating with the needle assembly for receiving withdrawn body fluid. The assembly comprising a hemostatic segment has a proximal end, a distal end, and a passageway extending therebetween. The hemostatic segment comprises a valve positioned in the passageway at the proximal end of the assembly and having an opening permitting passage of a wire guide therethrough. The distal end is sized and configured for leak-free engagement with the proximal end of the needle hub attachment assembly. The passageway is aligned with the needle assembly passageway and needle hub attachment assembly passageway to form a path for insertion of the wire guide into the body vessel. The distal end of the assembly comprising a hemostatic segment tapers to an endhole having a diameter substantially the same as the diameter of the wire guide.

The Osypka patent publication, on the other hand, discloses a vascular introducer assembly 10. Vascular introducer assemblies of this type are utilized for introducing a medical instrument therethrough, such as a pacemaker lead or a catheter. The Osypka device is not as a percutaneous insertion system within the meaning of the present claims, and is not capable of such use.

The device disclosed in Osypka comprises an introducer assembly that includes a dilator 28, an introducer sheath 18 for accommodating the dilator, a locking mechanism 24 for temporarily securing the dilator and the sheath to one another, and a hemostatic seal 58 for limiting egress from the introducer assembly. According to the patent publication, the dilator is inserted into a vessel over a guidewire 86 that has previously been inserted into the vessel. The guidewire is

inserted in conventional fashion, e.g., through the bore of a previously inserted needle. Following insertion of the guidewire, the needle is withdrawn, and the introducer assembly is introduced over the guidewire in well-known fashion. See, e.g., paragraphs [0006] and [0049] of Osypka.

The Examiner has identified certain structure in Osypka that is said to meet the limitations of the claimed insertion system. According to the Examiner (page 2 of the Office Action), introducer sheath 18 meets the limitation of a needle, introducer engagement hub 20 meets the limitation of a needle hub, sealing cap 22 meets the limitation of a needle hub attachment assembly, and dilator 28 meets the limitation of a hemostatic segment.

Applicants respectfully submit that the claimed percutaneous insertion system of claim 1 is quite different from the introducer assembly disclosed in Osypka. For example, the system of claim 1 includes a needle assembly as described above, the distal end of which comprises an elongated needle for percutaneous entry into a body vessel for withdrawing a body fluid therefrom. The Examiner cites a conventional introducer sheath 18 as meeting this limitation. However, the introducer sheath in Osypka is not structured for percutaneous entry into a vessel for withdrawing a body fluid. Rather, as Osypka points out (paragraph [0049]), the introducer assembly is inserted over a guidewire "as shown in FIG. 5 and as described in the above background." According to the Background,

> [0006] Typically, the percutaneous introduction of an introducer assembly is accomplished by first inserting a needle into the blood vessel at a desired location and its position is verified by observing fluid return or by a similar method. While the needle is held firmly in place, a guidewire is inserted through the needle cannula to the desired depth. The guidewire is then held in place and the needle is withdrawn. Pressure is applied on the puncture site in order to minimize blood loss. Next, the introducer assembly is threaded over the guide wire. The introducer assembly is grasped close to the skin surface and advanced through the tissue to the desired position. Then, the dilator and guidewire are removed, leaving the sheath installed. A lead,

> catheter or similar diagnostic or therapeutic device is then introduced into the sheath and advanced to the desired position. ...

Thus, it is clear that the introducer sheath identified by the Examiner in Osypka does not meet the limitation of a needle. Rather, as recognized in Osypka, it is still necessary to utilize a needle in order to properly place the Osypka introducer assembly.

The principles of law relating to anticipation are clear. "A claim is anticipated only if each and every element as set forth in the claim is found, expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987), *cert. denied*, 484 U.S. 827 (1987). Analysis of whether a claim is patentable over the prior art under 35 U.S.C. § 102 begins with a determination of the scope of the claim. The scope of the claim in a patent application is determined not solely on the basis of the claim language, but upon giving the claim its broadest reasonable construction in light of the specification *as would be interpreted by one of ordinary skill in the art. In re Am. Acad. Of Sci. Tech. Ctr.*, 367 F.3d 1359, 1364, 70 USPQ2d 1827, 1830 (Fed. Cir. 2004) (emphasis added). See also, *Ex parte Mary Smith*, Appeal No. 2007-1925, Board of Patent Appeals and Interferences, June 25, 2007, pages 6-7. One skilled in the art would never consider the introducer sheath of Osypka as comprising a needle for percutaneous entry into a body vessel for withdrawing a body fluid therefrom. In fact, the applicants in the Osypka application clearly did not make such an association when they stated that a needle must still be used to position the guidewire, prior to introduction of the sheath. Introducer sheaths and needles have separate functions in the medical arts, and one skilled in the art would not consider such devices to be interchangeable, or that the identification of one such device in a reference somehow meets the limitation of the other.

Similarly, Osypka does not meet the limitation of a needle hub attachment assembly. The Examiner has identified sealing cap 22 as meeting this limitation. The needle hub attachment assembly of claim 1 includes a passageway extending therethrough *and* a chamber communicating with the needle assembly for receiving withdrawn body fluid. One example of a chamber (26) is shown in Fig. 3. Sealing cap 22 of Osypka is a generally cylindrical body having an axial bore therethrough. At most, the sealing cap 22 has a passageway therethrough, as in the needle hub attachment assembly of claim 1. However, no chamber for receiving body fluid is present in the sealing cap.

Osypka also does not include an assembly comprising a hemostatic segment. According to claim 1, the assembly comprising a hemostatic segment has a proximal end, a distal end, and a passageway extending therebetween. The hemostatic segment comprising a valve is positioned in the passageway at the proximal end of the assembly and has an opening permitting passage of a wire guide therethrough. The distal end is sized and configured for leak-free engagement with the proximal end of the needle hub attachment assembly. The passageway is aligned with the needle assembly passageway and needle hub attachment assembly passageway to form a path for insertion of the wire guide into the body vessel. The distal end of the assembly comprising a hemostatic segment tapers to an endhole having a diameter substantially the same as the diameter of the wire guide.

The Examiner has identified dilator 28 of Osypka as meeting the limitation of the assembly comprising a hemostatic segment. Applicants respectfully point out that dilator 28 is very different from the recited element, both structurally and functionally, and would never be identified by one skilled in the art as meeting a limitation of the claimed assembly having a hemostatic segment. For example, according to the language of claim 1, the distal end of the assembly comprising a hemostatic segment is sized and configured for leak-free engagement with the proximal end of the needle hub attachment assembly. The distal end of the dilator 28

in Osypka extends into the vessel (Fig. 5), and is the distalmost feature of the introducer assembly. It is clearly not sized and configured for leak-free engagement with the proximal end of the needle hub attachment assembly, nor, in fact, is it configured for engagement with any other structure. Furthermore, the passageway of the assembly having a hemostatic segment is aligned with the needle assembly passageway and needle hub attachment assembly passageway to form a path for insertion of the wire guide into the body vessel. In the Osypka device, the passageway through the dilator comprises the path for insertion of the wire guide. It is not aligned with the other passageways to form the path as claimed. Finally, the distal end of the assembly comprising a hemostatic segment tapers to an endhole having a diameter substantially the same as the diameter of the wire guide. This is best shown in Fig. 5 of the present application, wherein distal end 42 tapers to endhole 43. According to the application:

> The tapered end of the inserter is sized such that it can be snugly inserted into the proximal end of the needle hub attachment assembly 20. Endhole 43 has a diameter that substantially matches the diameter of the wire guide to inhibit blood reflux through the device. However, the diameter of endhole 43 may be formed to be slightly larger than that of the wire guide to permit smooth insertion and/or extraction of the wire guide from the inventive system 10. Page 8, lines 18-23.

There is no teaching or suggestion in Osypka of this diametrical relationship between the dilator and a wire guide. The Examiner has identified Fig. 5 in Osypka as meeting this limitation, however upon review of this figure, Applicants dispute that it teaches a hemostatic segment that tapers to an endhole having a diameter substantially the same as the diameter of the wire guide. Rather, Fig. 5 merely appears to show a wire guide passing through a dilator. Further, Applicants respectfully submit that nothing in the specification of Osypka provides support for the Examiner's findings in this regard.

Thus, for at least the foregoing reasons, claim 1 of the present application is not anticipated by the Osypka publication. Claims 2, 7-10, 14, 16 and 29 depend, directly or indirectly, from claim 1 and include all of its limitations. Accordingly, these claims are not anticipated for at least the same reasons that claim 1 is not anticipated.

Claims 17, 18 and 21-24.

Independent claim 17 is also directed to a percutaneous insertion system. The insertion system of claim 17 includes a needle assembly having a first hemostatic segment, and an assembly comprising a second hemostatic assembly. The needle assembly has a proximal end, a distal end, and a passageway extending therebetween. The distal end comprises an elongated needle for percutaneous entry into a body vessel for withdrawing a body fluid therefrom. The assembly comprising a second hemostatic segment has a proximal end, a distal end, and a passageway extending therebetween. The distal end is sized and configured for leak-free engagement with the proximal end of the needle assembly. The passageway is aligned with the passageway of the needle assembly to form a path for insertion of a wire guide into the body vessel. The second hemostatic segment comprises a valve positioned in the passageway at the proximal end of the assembly, and having an opening permitting passage of the wire guide therethrough. The distal end of the assembly comprising a second hemostatic segment tapers to an endhole having a diameter substantially the same as the diameter of the wire guide.

As stated above, Osypka does not teach an elongated needle for percutaneous entry, a distal end of the assembly that tapers to an endhole having a diameter substantially the same as the diameter of the wire guide, or respective segments having passageways aligned to form a path for insertion of a wire guide. Further, Osypka does not teach a first hemostatic segment in a needle assembly. Thus, for at least the foregoing reasons, claim 17 of the present application is not anticipated by

the Osypka publication. Claims 18 and 21-24 depend, directly or indirectly, from claim 17 and include all of its limitations. Accordingly, these claims are not anticipated for at least the same reasons that claim 17 is not anticipated.

Claim 30.

Independent claim 30 is also directed to a percutaneous insertion system. The insertion system comprises a needle assembly and an assembly comprising a hemostatic segment. The needle assembly has a proximal end, a distal end, and a passageway extending therebetween. The distal end comprises an elongated needle for percutaneous entry into a body vessel for withdrawing a body fluid therefrom. The assembly comprising a hemostatic segment has a proximal end, a distal end, and a passageway extending therebetween. The distal end is sized and configured for leak-free engagement with the proximal end of the needle assembly. The passageway is aligned with the needle assembly passageway to form a path for insertion of a wire guide into the body vessel. The hemostatic segment comprises a valve positioned in the passageway at the proximal end of the assembly. The valve tapers in a distal direction to an endhole having a diameter substantially the same as the diameter of the wire guide.

As stated above, Osypka does not teach an elongated needle for percutaneous entry, a distal end of the assembly that tapers to an endhole having a diameter substantially the same as the diameter of the wire guide, or respective segments having passageways aligned to form a path for insertion of a wire guide. Thus, for at least the foregoing reasons, claim 30 of the present application is also not anticipated by the Osypka publication.

Sec. 103(a) rejections.

Claims 3, 4, 12, 19 and 32.

Claims 3, 4, 12, 19 and 32 were rejected under 35 U.S.C. §103(a) as being unpatentable over Osypka in view of Raulerson (USP 6,551,281). Raulerson was cited for teaching a guidewire advancer comprising a guidewire holder that is preloaded with a guidewire fastened in a loop so that the guidewire can be easily manipulated by the user and remain sterile while it is inserted into the patient. Claims 3, 4 and 12 depend from claim 1, and therefore include all of its limitations, including the limitations relating to the needle assembly, needle hub attachment assembly, and assembly comprising a hemostatic segment, as described in greater detail hereinabove. These limitations are neither taught nor suggested in Raulerson. Claim 19 depends from independent claim 17, and claim 32 depends from independent claim 30. These claims include all of the limitations of the respective independent claim, including the limitations relating to the needle assembly and the assembly comprising a hemostatic segment, as described above. Thus, claims 3, 4, 12, 19 and 32 are not obvious in view of the cited combination.

Claims 11, 20, 31.

Claims 11, 20 and 31 were rejected under 35 U.S.C. §103(a) as being unpatentable over Osypka in view of Padilla et al (USP 5,984,895). Padilla was cited for teaching a vascular blood flashback containment device that is transparent to allow for the visualization of blood. Claim 11 depends from claim 1, claim 20 depends from claim 17, and claim 31 depends from claim 30. Therefore, these dependent claims include all of the limitations of the respective independent claims, as recited above. These limitations are neither taught nor suggested in Padilla. Thus, claims 11, 20 and 31 are not obvious in view of the cited combination.

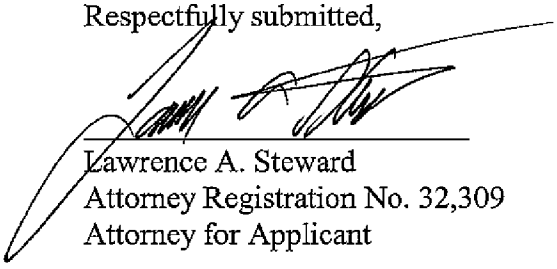
Claim 13.

Claim 13 was rejected under 35 U.S.C. §103(a) as being unpatentable over Osypka. Claim 13 depends from claim 1, and includes the additional limitation that at least one of the leak-free engagements comprises a luer lock assembly. Since claim 13 depends from claim 1, it includes all of the limitations of claim 1 as previously described herein. As stated above, Osypka does not teach or suggest such features. Accordingly, claim 13 is not obvious in view of Osypka.

Conclusion:

Based upon the foregoing, Applicants respectfully submit that the grounds for rejection of the claims have been overcome, and that all claims 1-4, 7-14, 16-24 and 29-32 are in condition for allowance. Accordingly, Applicants request the prompt issuance of a Notice of Allowance. If the Examiner believes that prosecution of this application may be advanced by way of a telephone conversation, the Examiner is respectfully invited to telephone the undersigned attorney.

Respectfully submitted,



Lawrence A. Steward
Attorney Registration No. 32,309
Attorney for Applicant

LAS/cbw
BRINKS HOFER GILSON & LIONE
CUSTOMER NO. 27879
Telephone: 317-636-0886
Facsimile: 317-634-6701